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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,190	12/20/2006	Pablo Vicente Escriba Ruiz	U 016243-8	7142

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,190	ESCRIBA RUIZ, PABLO VICENTE	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-8 ARE PRESENTED FOR EXAMINATION

Applicant's Preliminary Amendment filed April 7, 2006 and Information Disclosure Statement filed May 14, 2008 have been received and entered into the application.

Accordingly, claim 3 has been amended and claims 6-8 have been added. Also, as reflected by the attached, completed copy of form PTO-1449, (1 sheet), the cited references have been considered.

Specification

The specification at page 1, after line 2 is objected to under MPEP § 201.11 as being incomplete. The heritage of the present application needs to be inserted after line 2 of page 1 of the specification.

Appropriate correction is required.

Claim Interpretation

Given the construct of the claims as originally presented, (i.e., in the preliminary amendment), the Examiner will interpret these claims as methods for the manufacture of food additives and/or food in general.

Should Applicant attempt to amend the claims, attention is directed to MPEP § 818.02(a) wherein it is stated that:

"The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant ... Subsequently presented claims to an invention other than that acted on should be treated as provided under MPEP § 821.03, (i.e., such claims will be withdrawn from consideration as being directed to a non-elected invention).

Accordingly, should Applicant attempt to amend the claims to an invention directed to anything else than a manufacture of a food additive or food, such will be withdrawn from consideration based on the "election by original presentation" concept set forth in the MPEP, *supra*.

Claim Rejection - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for manufacturing a food additive or food useful for the treatment and control of hypertension and/or obesity, does not reasonably provide enablement for the manufacture useful for the prevention of the same conditions. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an amount of experimentation that is undue.

In particular, Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an article of manufacture comprising an the claimed carboxylic acids for the control of hypertension and/or obesity, does not reasonably provide enablement for the manufacture of a food or food additive useful the prevention hypertension and/or obesity, i.e., where either hypertension or obesity is ever kept from ever occurring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The burden of enabling the prevention of diseases/conditions such as hypertension and/or obesity would be much greater than that of enabling the treatment of such conditions where, upon administration of the appropriate active agents, obesity and/or hypertension are controlled, i.e., if such agents were not taken, then hypertension and/or obesity would be present. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing of such conditions or how a patient could be kept from ever being susceptible to these conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing hypertension and/or obesity or even how to select a patient population who does not suffer from hypertension and/or obesity, but is still at risk for developing the same.

Further, it is highly unlikely, and the Office would require experimental evidence to support the contention, that the manufacture of a food or food additive containing the

claim specified actives could actually prevent hypertension and/or obesity. The specification fails to enable one of ordinary skill in the art to practice and use the compositions/article of manufacture in the present claim for preventing the above conditions.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having a success which would require undue experimentation by the skilled artisan. Since such success is not reasonably possible with most diseases/disorders known to the artisan, especially those having etiologies and pathophysiological manifestations as complex/poorly understood as hypertension and/or obesity, the specification is viewed as lacking an adequate enabling disclosure of the same.

Also, factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. All factors need not be addressed. However, when the appropriate factors from those above are applied to the present application are considered and weighed, it is the examiner's position that the present specification would only enable the skilled artisan to manufacture a food or food additive useful for treating or controlling hypertension and/or obesity.

Summary

As the discussion above establishes, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that prevention of hypertension and/or obesity could be achieved. In order to actually achieve the prevention of such, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Also, given that Applicant has failed to demonstrate that hypertension and/or obesity could actually be prevented, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. This is so because the skilled artisan would view the manufacture of a food or food additive useful for preventing these conditions unpredictable based on knowledge in the art.

Accordingly, claims 1-8 are deemed properly rejected.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 provide for the use of the claimed aliphatic acid for various purposes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
Art Unit 1614

June 17, 2009